

# **USUHS FORM 3206**

## **ANIMAL STUDY PROPOSAL**

### **FORM INSTRUCTIONS**

**FILL OUT ONLY THE COVER SHEET AND THE OUTLINE AT THE END OF THESE INSTRUCTIONS.**

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**THE FIRST ELEVEN PAGES OF THIS PACKAGE ARE INSTRUCTIONS ONLY THAT DETAIL HOW TO FILL OUT THE ACCOMPANYING COVER SHEET AND OUTLINE (Form pages).**

The "fill-in-the-blank" format of the form is designed to be completed using a word processing program, i.e., WordPerfect, WordStar, Microsoft Word, etc. In this way, you are not limited by the space provided and changes or modifications can be quickly and easily made.

Specific questions in this form are a result of the requirements of the Animal Welfare Act (AWA), DoD Regulations, and/or animal welfare guidelines. Please respond to each question/paragraph. Portions of the form not applicable to your particular protocol, i.e., there is no surgery or no prolonged animal restraint, should be marked "N/A". If SOPs or other documents are readily available to the LARB, these may be referenced to assist in describing specific procedures. It is critical that only animal studies or procedures documented in an approved protocol are performed in the organization. Additionally, Principal Investigators or other animal users should maintain accurate experimental records and be able to provide an audit trail of their animal expenditures and use that correlates to approved protocols.

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**PROTOCOL COVER SHEET:** Requires one signature from the Primary Investigator and a signature from the person responsible for scientific review. Coordination signatures from an Attending Veterinarian and a Statistician are highly recommended. This Protocol Cover Sheet can also hold any additional information deemed necessary by the organization (Co-Investigators, Coordinating Departments, Laboratory Animal Review Board (LARB) Chair, Biosafety Review, etc.).

#### **CHECK THE FOLLOWING:**

- ☐ New (First Submission or Major Modifications\*\* to Previously Submitted Protocol)  
New Animal protocol number: \_\_\_\_\_ (DLAM will assign)
- ☐ Previously Submitted Protocol:  
Old Animal protocol number: \_\_\_\_\_ Old REA protocol number: \_\_\_\_\_  
(Animal protocol numbers begin with your department abbreviation while REA protocol numbers begin with "G", "F", "C0", "R0", "T0", "E0" or "M0". For example, "ANA00001" would be an Animal protocol number while "C07001" would be a REA protocol number.)  
Protocol which has been reviewed and approved by USUHS LARB and is now being re-submitted for funding to the same or a different agency.
- ☐ No modification
- ☐ Minor modification (indicate revisions with a ***bold and italic type font***)  
Changes include, but are not limited to:
- Moderate increase in number of animals
  - Change in personnel, e.g., technicians, Co-investigators
  - Change in euthanasia procedure
  - Change in procedure location
  - Providing tissue from euthanized animals to others not listed on protocol
  - Transfer of same animal species/strain from one of your approved protocols to another of your approved protocols (no increase in pain category)
  - Transfer of same animals species from one of your approved protocols to another investigator's approved protocols (no increase in pain category, same strain/species)
  - Minor procedural change (experimental design); additional chemical agent similar to those already approved

\*\* Major modification is considered a new Protocol.

Significant changes include, but are not limited to:

- Changes in objectives of the original research
- Change in non-survival vs. survival surgery status
- Change in pain category to more painful
- Change in species/change in strain
- Significant procedural change
- Addition of invasive procedure
- Change in protocol PI
- Withdrawal of analgesia/antibiotics

**ANIMAL PROTOCOL TITLE:** If the title does not include the animal species, please include it in parenthesis.

**PRINCIPAL INVESTIGATOR:** Typed name, signature, and date.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

**DEPARTMENT:** USUHS department.

**TELEPHONE:** Office/lab telephone.

**SCIENTIFIC REVIEW:** Type name. Signature verifies that this proposed animal use protocol has received appropriate peer scientific review and is consistent with good scientific research practice. (No response is required to the title paragraph of this section)

\_\_\_\_\_  
Research Unit Chief/Department Head Signature

\_\_\_\_\_  
Date

**COORDINATION:** Name, date, and signatures for the appropriate person(s) or office(s). The signature of the attending/consulting veterinarian is required for all Pain Category D or E proposals prior to submission of the proposal to Research Administration. The signature of the statistician is highly recommended. (No response is required to the title paragraph of this section)

- A. **LAM Pre-Review Certification:** Laboratory Animal Medicine has pre-reviewed this protocol before submission to REA.

\_\_\_\_\_  
Laboratory Animal Medicine Pre-Reviewer Signature

\_\_\_\_\_  
Date

- B. **Attending/Consulting Veterinarian:** (Example) The attending/consulting veterinarian has reviewed the protocol and was consulted in the planning of procedures that require veterinary input, i.e., an unalleviated pain procedure (Pain Category D or E). In addition, the veterinarian/veterinary medicine department has assisted with coordination for veterinary support to the protocol. No response is required to the title paragraph of this section.

\_\_\_\_\_  
Attending/Consulting Veterinarian Signature

\_\_\_\_\_  
Date

- C. **Statistician:** A person knowledgeable in statistics has reviewed the experimental design. No response is required to the title paragraph of this section.

\_\_\_\_\_  
Statistician Signature

\_\_\_\_\_  
Date

**(-- Start Separate Page --)**

**ANIMAL PROTOCOL NUMBER:**

**PRINCIPAL INVESTIGATOR:** Type name

**DEPARTMENT:**

**PHONE:**

**ANIMAL PROTOCOL TITLE:** Must include animal species being used.

**CO-INVESTIGATOR(S):** Type name(s).

**TECHNICIAN(S):** Type name(s).

I. **NON-TECHNICAL SYNOPSIS:** A brief narrative description of the proposal or idea that is easily understood by non-scientists.

II. **BACKGROUND:**

A. **Background:** This should include a brief statement of the requirement or need for the information being sought. Lengthy explanations are not required. Typically, the "literature or the experience that led to the proposal will be briefly reviewed" (USUHS Instruction 3203) and a description of the general approach should be provided. Unnecessary duplication of effort should be strictly avoided.

B. **Literature Search:** This search must be performed to prevent unnecessary duplication of previous experiments. A search of Federal Research In Progress (FEDRIP) and Defense Technical Information Center (DTIC) databases is required for all research performed at Department of Defense facilities. An additional search of the scientific literature (MEDLINE, GRATEFUL MED, MEDLARS, AWIC, etc.) is highly recommended.

1. **Literature Source(s) Searched:**

2. **Date and Number of Search:** Searches must be less than 6 months old at the time of submission

3. **Key Words of Search:**

4. **Results of Search:** Provide a narrative description of the results of the literature search(s).

III. **OBJECTIVE/HYPOTHESIS:** In non-technical terms, state the objective of this protocol or the hypothesis to be accepted or rejected.

IV. **MILITARY RELEVANCE:** With regard to military needs and mission requirements, this paragraph should provide a brief and succinct military justification for the research. If applicable, state the Science and Technology Objective (STO) that this work supports. For USUHS Protocols the following statement may be inserted: "A quality medical education is dependent on providing the best faculty possible. This is in part made possible by recruiting faculty who are experts in their fields and who have diverse backgrounds in their research projects. These qualities help USUHS to provide an up-to-date educational opportunity to further federal physicians."

V. **MATERIALS AND METHODS:**

A. **Experimental Design and General Procedures:** Provide a "**complete description** of the proposed use of animals." This section should succinctly outline the formal scientific plan and direction for experimentation. If several experiments or sequential studies are to be included in the protocol, description of the experimental design for each separate experiment should be contained in sub-parts to this section. The length and detail required in this section depends largely on the complexity of the

study. However, **a clearly understandable description of the numbers of animals and their distribution into experimental groups is essential.** The number requested should be the minimum numbers necessary to complete the study; but, must be sufficient to yield meaningful results. If too few animals are requested and statistical significance is not achieved, the animals will have been misused. Be certain to include animals necessary for controls or technique development, etc. If the design is complex, a summary table or flow chart showing the distribution of animals by experimental group should be included. **The total number of animals required for the study is listed in section V.B.4. It is critical that reviewers of this protocol are able to follow your reasoning and calculations for the number of animals required, and can verify that the experimental design clearly supports the number of animals requested.**

1. Experiment 1:
2. Experiment 2:

(add experiments as required)

**B. Laboratory Animals Required and Justification:**

1. **Non-Animal Alternatives Considered:** Were alternatives to animal use considered? **No study using animals should be considered prior to the elimination of all reasonable possibilities that the question might be adequately answered using other than animal means, i.e., computer modeling, cell cultures, etc.**
2. **Animal Model(s) and Species Justification:** It is important that you adequately justify that animals are necessary for attainment of the research/training objectives. Moreover, justify the selection of this particular animal model. Investigators should use the least sentient species that will permit the attainment of research objectives. Why was this particular animal chosen? Were there other animal models considered that are lower on the phylogenetic scale (e.g., mice instead of rabbits)? Is there a unique quality or usefulness about this species that warrants its selection for use?
3. **Total Number of Animals Required and Justification for that Number:** Genus and species must be included. Strain/Stock: If inbred or specialized animals are required, please use proper terminology. Source/Vendor: Provide a preferred source for the animals. Procurement of animals from non-USDA licensed sources requires an exception to policy. Enter the source/vendor's USDA license number if available. Special Considerations: Specialized requirements for the research animals should be reflected here, i.e., SIV or herpes antibody free, Pasteurella free, etc. Length of stay (for each species). Estimate the total number of animal days.

<b>Genus &amp; Species</b> _____	<b>Stock/Strain</b> _____
<b>Sex</b> _____	<b>Age/Weight/Size</b> _____
<b>Source/Vendor</b> _____	<b>Holding Location(s)</b> _____

**Number of Animals requested/total number of housing days required:**

	<u>Animals Requested</u>	<u>Housing Days</u>
Year 1	_____	_____
Year 2	_____	_____
Year 3	_____	_____

**Special Considerations:** \_\_\_\_\_

**Other:** \_\_\_\_\_

**Justification for that Number:** \_\_\_\_\_

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**(Note: This table should be blocked and copied, and repeated for each species requested)**

This section requires the species, total number of animals to be used, and the total number of days the animals will require housing during the project. The number requested here should **match exactly** those described in para V. A., Experimental Design & General Procedures in the MATERIALS AND METHODS section. Keep in mind the number requested should be the minimum numbers necessary to complete the study, but must be sufficient to yield meaningful results. If too few animals are requested and statistical significance is not achieved, the animals will have been misused. Be certain to include animals necessary for controls or technique development, etc. If additional animals are needed due to technical or unavoidable circumstances, or to exploit a serendipitous finding, follow LARB procedures for requesting approval for additional animals. Less than 10% of the total number of animals requested in the original protocol is a minor modification; more than 10% is a major modification.

**4. Refinement, Reduction, Replacement:** The DoD must provide specific examples of its alternatives initiatives in the annual report to Congress. Does this protocol have any provisions that would qualify it to be identified as one that refines, reduces or replaces (3 R's) the use of animals? For example, does your study use statistical tests that require fewer animals, i.e., a modified LD50 test like Thompson & Weil, or are you using cell cultures, computer modeling or any other technique that will influence the numbers of animals required? Are you using animals lower on the phylogenetic scale? Please provide a short description of the features that you feel qualify the study as one that employs one of the "3 R's," or give a negative reply. No response is needed under the title paragraph of this section. **This information should be captured in such a way that it can be included in the DoD annual report submission.**

- a. **Refinement:** The use of analgesia or the use of remote telemetry to increase the quality and quantity of data gathered or adjusted early endpoint for the animals are examples of refinements.
- b. **Reduction:** Use of shared control groups, preliminary screening in non-animal systems, or innovative statistical packages are examples of reductions.
- c. **Replacement:** Non-animal systems that eliminate the use of animals are examples of replacement.

**C. Technical Methods:** These should be presented in sufficient detail, documented or referenced, so that the LARB can adequately review the procedure and obtain a clear understanding of what is to be done, how the animal will be handled, and make a reasonable determination as to whether this proposed use of laboratory animals is in compliance with DoD regulations, guidelines, and federal law. No response is needed under the title paragraph of this section.

- 1. **Prolonged Restraint:** Describe and justify in detail any prolonged restraint (greater than three hours) intended for use during the study, e.g., primate chairs, restraint boards, metabolism cages, etc. Also describe habituation procedures for the prolonged restraint. This section is not intended for short-term actions such as rabbit restraint for bleeding, etc. If there is prolonged restraint involved, who will be restraining the animals, and for how long?
- 2. **Surgery:** Major operative procedures on non-rodent species, i.e., rabbits, monkeys, etc., should be conducted only in dedicated facilities intended for that purpose, and operated and maintained under aseptic conditions. Non-major operative procedures and all rodent surgery do not require a dedicated facility, but must be performed using aseptic technique, i.e., surgical gloves, mask, sterile instruments. A major operative procedure is one that "penetrates and exposes a body cavity, or causes permanent impairment of physical or physiological function." The animal care unit personnel should assist in defining the

requirements of this portion of the law if necessary. No response required under the title paragraph of this section.

- a. **Procedure:** Describe in detail any surgical procedures planned.
- b. **Pre- and Postoperative Provisions:** Detail the provisions for both pre- and postoperative care, including provisions for post-surgical observations. Also include the provider of that care, and the location for the postoperative care.
- c. **Location:** Give the location/room # for the proposed surgical procedure.
- d. **Multiple Survival Surgery Procedures:** If multiple major operative procedures on the same animal are intended, they must be adequately justified for scientific reasons by the P.I. in writing.

(I) **Procedures:**

(2) **Scientific Justification:**

3. **Animal Manipulations:** Any injections, sampling procedures, or other manipulations of the animals necessary for the execution of the study must be described if not listed in section V. List needle sizes, routes of injection or withdrawal and anatomical location, e.g., 21 ga needle, SQ, IM, femoral vein, jugular vein, etc., or the proposed method so that a reasonable evaluation of the appropriateness of the procedure can be made. You may wish to rearrange the subparagraphs of this section to suit your protocol. No response is needed under the title paragraph of this section.
  - a. **Injections:** There is no need to duplicate specific information already provided in section V.C.7.b., the Pain Alleviation, anesthesia/analgesia section of the proposal. Include dosage, route, site, and needle size for **all** injections given.
  - b. **Biosamples:** Cerebral taps, blood sampling, etc. List amounts taken and method for sampling. This includes all tissue harvested when animals are euthanized.
  - c. **Animal Identification:** Microchip, tattoo, ear tags, cage cards, etc. Indicate the applicable method or methods.
  - d. **Behavioral Studies:** Fully describe any intent to use aversive stimuli, food or water deprivation, etc, that would impact upon the animals in this study.
  - e. **Other procedures:** EKG's, radiology, aerosol exposure, etc.
  - f. **Location where procedure will take place.** Bldg \_\_\_\_\_ Rm \_\_\_\_\_
4. **Adjuvants:** List any adjuvants and your plan for their use. Provide dosages & route.
5. **Study Endpoint:** What is the projected end point or termination of the study for the animals? Is death, euthanasia, or recovery expected; and what is the specific plan for determining when the animal experimentation phase will be stopped? You should ensure that unnecessary pain or distress is prevented by carefully considering "When is the experimental question answered?" so that the animals can be removed from the study as soon as feasible. Explain the plan for the disposition of surviving animals. **You must specifically address and justify any proposed use of death as an endpoint. Death as an endpoint indicates that animals will sicken and die.**
6. **Euthanasia:** Explain the plan for euthanasia of the animals at the completion of the study and who will perform the procedure. The AWA defines euthanasia as "humane destruction of an animal by a method that produces rapid unconsciousness and subsequent death without

evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." The current AVMA guidelines for euthanasia must be followed. Exceptions to the AVMA guidelines will be considered by the LARB on a case-by-case basis. Exceptions must be scientifically justified by the P.I. in writing. The attending veterinarian will assist in selecting the best method for euthanasia if requested. Cervical dislocation or decapitation without anesthesia must be scientifically justified and specific training in the procedure.

7. **Pain:** The law defines a painful procedure as one that would "reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures." **If a procedure involves pain or distress, the P.I. must consult with the attending veterinarian.**

a. **USDA APHIS Form 7023 Pain category:**

This information is reported by the organization to the USDA on USDA APHIS Form 7023. **The P.I. or primary user should estimate the number of animals that will be counted in each pain category.** There are many situations where there are animals in more than one category, i.e., control animals. If more than one Species is requested in the proposal, reflect those animals in a duplicate table in this paragraph. **The total numbers reflected in these three categories must add up to the number and percent of animals requested for the entire protocol in paragraph V.B.4.**

(1) **No Pain** \_\_\_\_\_ (#) \_\_\_\_\_ % (Column C)

Studies involving no pain or distress beyond that expected on a momentary nature such as would occur with an injection, a deep palpation, grooming activities, etc.

(2) **Alleviated Pain** \_\_\_\_\_ (#) \_\_\_\_\_ % (Column D)

Procedures wherein anesthesia or analgesia will be administered to avoid or alleviate pain or distress. General anesthesia given for surgical preparations, or the use of analgesia or anti-inflammatories would be examples for this category.

(3) **Unalleviated Pain or Distress** \_\_\_\_\_ (#) \_\_\_\_\_ % (Column E)

Procedures where alleviation of pain or distress are contraindicated for some justifiable reason such as would confound the experimental results if drugs relieving pain were administered. Detailed justification for putting animals into this category is required below in para V.C.1.d.

- b. **Pain Alleviation:** The attending veterinarian should be able to provide assistance in completing this section of the proposal.

(1) **Anesthesia/Analgesia/Tranquilization:** Describe the methods or strategies planned to alleviate pain or distress. If pain alleviation is planned, specify who will be administering the analgesics, anesthetics, or tranquilizers during the study. Provide agent, dosage, route & site, indication, needle size, etc.

(2) **Paralytics:** No use of paralytic agents without anesthesia is allowed.

c. **Alternatives to Painful Procedures:**

(1) **Source(s) Searched:** e.g., AWIC, AGRICOLA, CAAT, MEDLINE, etc.

(2) **Date of Search:**

(3) **Key Words of Search:** e.g. Pain, surgery,

**(4) Results of Search:** Provide a narrative description of the results of the alternatives literature search.

"Research facilities will be held responsible, if it is subsequently determined that an alternative to a painful procedure was available to accomplish the objectives of the proposed experiment." The Animal Welfare Act specifically states that the **"P.I. must provide a narrative description of the methods and sources, e.g., the Animal Welfare Information Center, MEDLINE, LIFE SCIENCES ABSTRACTS, AGRICOLA, AND BIOSIS that he/she used to determine that alternatives to the painful procedure were not available."** It is a requirement to perform the alternatives literature search and painful procedure justification even when animals are placed in the alleviated pain category (Column D).

- d. Painful Procedure Justification:** Procedures causing more than transient or slight pain that are unalleviated, must be justified on a scientific basis in writing by the P.I. The pain must continue for only the necessary period of time dictated by the experiment, and then be alleviated, or the animal humanely euthanized. This paragraph must be completed if there are any animals listed in either the alleviated (Column D) or the unalleviated pain or distress (Column E) category in para V.C.1. **The P.I. must consult with the attending veterinarian or his or her designee in the planning of both alleviated and unalleviated painful procedures, and state it here.**

**D. Veterinary Care:** Attending veterinary care of lab animals receives particular emphasis in the AWA. The attending veterinarian of your facility will assist P.I.s with preparing this section if requested. No response is necessary to the title paragraph of this subsection.

- 1. Husbandry Considerations:** The law specifically states that animal housing and living conditions must be appropriate to their species, and contribute to their health and comfort. Describe husbandry or refer to SOP. If known, list the location the animals will be routinely housed and the length of housing requirement. Personnel in the animal care unit should be able assist P.I.s in the preparation of the protocol sections dealing with animal care issues.
  - a. Study Room:** If stay exceeds 12 hours.
  - b. Special Husbandry Provisions:** Micro-isolators, metabolic cages, etc.
- 2. Attending Veterinary Care:** Will the animals be observed daily or more frequently, and by whom? What is the plan if the animal becomes ill or debilitated during the study and requires supportive therapy? Will the animal be euthanized if it becomes critically ill or comatose, and by whom (study end point adjustment)? Justification for not providing supportive care for clinically ill animals is necessary.
- 3. Enrichment Strategy:** Written justification for restricting enrichment programs or activity programs of dog, cat, or nonhuman primates must be provided.
  - a. Dogs:** Do you have any reason to restrict activity programs for dogs on this protocol that might be implemented by the animal care unit to comply with federal welfare regulations? If yes, justify.
  - b. Non-Human Primates:** Do you have any reason to prohibit environmental enrichment or enhancement strategies that might be implemented by the animal care unit to comply with federal welfare regulations? If yes, justify.
- 4. Antibody Production Texts (such as RAP or MAP) are available for testing transplantable tissues/tumors or cell lines. Contact the LAM staff if you are in need of this service.**

**E. Data Analysis:** List the statistical test(s) planned or the strategy intended to evaluate the data.



F. **Investigator and Technician Qualifications/Training:** List those animal procedures or manipulations described in the protocol that will be performed by each investigator or technician, and their training or qualifications to perform these procedures. Personnel conducting the "hands-on" animal procedures described in the protocol must be identified and appropriately trained and qualified to perform that procedure. **This is NOT questioning the P.I.'s PROFESSIONAL qualifications to conduct the research, but rather a requirement that personnel actually performing the research animal manipulations are technically competent, and thus are not inflicting unnecessary pain, distress, or injury to an experimental animal due to inexperience or improper technique.** Contact your attending veterinarian for assistance with this requirement.

VI. **BIOHAZARD/SAFETY:** Provide a list of any potential biohazards associated with this proposal, e.g., viral agents, toxins, radioisotopes, oncogenic viruses, chemical carcinogens, etc. Explain any safety precautions or programs designed to protect personnel from biohazards, and any surveillance procedures in place to monitor potential exposures.

VII. **ASSURANCES:** The law specifically requires several written assurances from the P.I. It states that "research facilities will be held responsible if it is subsequently determined that an experiment is unnecessarily duplicative, and that a good faith review of available sources would have indicated as much."

This section will state -- As the Primary Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

- A. **Animal Use:** The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a deviation is specifically approved by the LARB.
- B. **Duplication of Effort:** I have made a reasonable, good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
- C. **Statistical Assurance:** I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal, and that the "minimum number of animals needed for scientific validity are used."
- D. **Biohazard/Safety:** I have taken into consideration, and I have made the proper coordination regarding all applicable rules and regulations regarding radiation protection, biosafety, recombinant issues, etc., in the preparation of this protocol.
- E. **Training:** I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused as a result of the procedures/manipulations.
- F. **Training:** I verify that I have attended an approved (USUHS) Investigator Training Course.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

G. **Training:** The following personnel will attend the next approved USUHS Investigator Training Course:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

H. **Responsibility:** I acknowledge the inherent moral and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R" which the DoD has embraced, namely, "Responsibility" for implementing animal use alternatives where feasible, and conducting humane and lawful research.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

- I. **Painful Procedures:** (Include only if conducting research that will cause more than slight or momentary pain or distress [Column D or E by USDA classification] the following statement must follow.) **I am conducting biomedical experiments which may potentially cause more than momentary or slight pain or distress to animals that WILL BE relieved or WILL NOT (circle one) be relieved with the use of anesthetics, analgesics and/or tranquilizers.** I have considered alternatives to such procedures; however, using the methods and sources described in the protocol, I have determined that alternative procedures are not available to accomplish the objectives of the proposed experiment.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

- VIII. **ENCLOSURES:** (Available for the attachment of the results of any literature searches, SOPs, references, or other documents pertinent to the protocol that you may wish to include. Local LARB's should determine specific items to be included here.)

A. **Literature Searches:** DTIC, MEDLINE, AGRICOLA, etc.

B. **Pathology Addendum:** Optional information

C. **Pain Scoring Guidelines:**

D. **Adjuvant Policy:**

(-- Start Separate Page --)

- IX. **PROTOCOL ABSTRACT:** An abstract must be submitted with this protocol. This information must be submitted for entry into the publicly accessible Department of defense Biomedical research (DTIC, MATRIS Data Base) as required by Congress. This site may be accessed at Website "http://dticam.dtic.mil/www/welcome.html". This abstract must include the following:

A. **Animal Protocol Number:** (if new, leave blank) \_\_\_\_\_

B. **Animal Protocol Title:** Must include animal species being used.

C. **Principal Investigator:** Name and Department (or facility, if not at USUHS) affiliation.

D. **Performing Organization:** The name of the activity where the protocol work is accomplished. This may include the site(s) at which a teaching protocol is conducted. Uniformed Services University of the Health Sciences

E. **Funding:** This is the proposed funding for the entire protocol for the current fiscal year. The funding includes all costs for the protocol to include civilian salaries, costs of animals, cost of materials, etc. All costs related to the protocol are included EXCEPT military salaries.

F. **Objective and Approach:** This is a general summary of the protocol work. The work should be clearly stated in general lay-terms, recognizing the information is available to the public. An acceptable abstract should contain a sentence or two for the introduction and general statements as to the usefulness of the work. Two or three sentences regarding methods (to include the different species of animals used and the statistics for the evaluation of the data). One sentence should include your attempt to employ the three R's (reduction, replacement, and refinement) in the use of animals. Three of four sentences should address the general approach taken in the protocol.

- G. Indexing Terms (Descriptors):** List of all indexing terms or key words. If any animal work is done in the protocol, the key words will contain "animals" and the term for each type of animal used (e.g., guinea pigs, rats, mice).

***DO NOT RESPOND TO TITLE PARAGRAPHS***